

## REMARKS

This Amendment and Reply is filed in response to the Office action mailed December 2, 2003. It is being filed within the shortened three month period set for response and no Petition for Extension of Time or fee is therefore required.

In the amended Figures 4, 8B, 17 and 22, corrections have been made in accordance with the Examiner's comments concerning omitted and extraneous reference numerals. Specifically, Figure 4 has been amended to remove reference to element 512 from the drawing. Figure 8B has been amended to include a reference to element 96 indicating an internal cavity, as described in the specification at page 22, line 5. In Figure 17, reference to element 310' has been deleted. In Figure 22, reference numeral 338' has been changed to reference numeral 438, indicating the retainer assembly or mechanism as described in the specification at page 37, lines 29-30. In addition, reference numeral 462 has been removed from Figure 22.

The Specification has been amended to correct minor typographical errors.

Claims 20, 21, 23, 24, 26-32 and 40-56 are currently pending in this application. Claims 1-19 were previously cancelled as a result of preliminary amendments. Claims 20, 21, 23, 24 and 26-32 are currently amended; previously withdrawn claims 22, 25 and 33-36 are cancelled; and previously pending claims 37-39 are currently cancelled. Claims 40-56 are new.

Independent claim 20 has been amended to specify an adjustable diameter cutter having a plurality of radially pivotable cutting blades, wherein each of the cutting blades has a beveled edge for cutting. This amendment is made for purposes of clarification and to more clearly distinguish the applicant's claimed invention from the prior art relied upon for rejection. Claim 21 has been amended to specify that the material removal ports permit flow through when the adjustable diameter cutter is expanded. Claim 23 has been amended to specify that the fixed diameter cutter has a plurality of fixed cutting blades. Claim 24 has been amended to specify that the fixed cutting blades of claim 23 have beveled edges. Claim 26 has been amended to depend from claim 20, and to clarify that stop faces contact the cutting blades when the cutting blades are in a smaller diameter condition. Claim 27 has been amended to depend from claim 20, and to specify that support faces contact the cutting blades when the cutting blades are in a larger diameter condition.

Independent claim 28 has been amended to specify an expandable diameter cutter having a plurality of blades pivotable between a tangential orientation and a radial orientation. This

amendment is made for purposes of clarification and to more clearly distinguish the applicants' claimed invention from the prior art relied upon for rejection. Claim 29 has been amended to provide clarified claim language. Claim 30 has been amended to specify that the material removal ports are located between the cutting blades and permit flow through when the cutting blades are positioned in a radial orientation. Claims 30 and 31 have been amended for purposes of clarification and to use language corresponding to that used in independent claim 28.

New claim 40 specifies that the fixed diameter cutter is positioned distally from the adjustable diameter cutter. This aspect of applicants' claimed invention was previously recited in claim 23. Claim 41 specifies that the fixed diameter cutter has a frusto-conical cross-sectional configuration and a series of raised cutting flutes. This aspect of applicants' claimed invention is described in the specification, for example, at page 32, lines 13-14. Claim 42 recites a device of claim 20 or 28 additional comprising a temperature sensor. This aspect of applicants' claimed invention is described in the specification, for example, at page 6, lines 21-24. Claim 43 specifies that the drive shaft is a multi-filar metallic coil, which is described in the specification, for example, at page 17, lines 21-29. Claim 44 recites a magnetic coupler assembly mounted to the drive shaft to provide detachable coupling of the drive shaft to a drive train. This aspect of applicants' claimed invention is described in the specification, for example, at page 15, line 6 – page 16, line 2. Claim 45 specifies that the drive shaft comprises a helical coil having a polymer layer sealing an outer and/or inner surface, and claim 46 specifies that the polymer layer comprises PFTE. These aspects of applicants' claimed invention are described in the specification, for example, at page 17, lines 21-29.

Claim 47 recites that the cutting blades are arranged in a radially symmetrical configuration. This aspect of applicants' claimed invention is described in the specification, for example, at page 29, lines 5-7. Claim 48 describes a bearing assembly coupling the cutter assembly to a conduit catheter. This aspect of applicants' claimed invention is described in the specification, for example, at page 31, lines 1-17. Claims 49 and 50 specify certain materials from which the cutting blades are constructed. These aspects of applicants' claimed invention are described in the specification, for example, at page 30, lines 1-3. Claim 51 specifies that the beveled edges of the blades are sharpened, which is described in the specification, for example, at page 21, lines 11-12. Claims 52 and 53 specify various specific structures of the cutter assembly which are described in the specification, for example, at page 31, line 25 – page 32,

line 12. Claim 54 recites circumferentially interspaced ports that are described in the specification, for example, at page 34, lines 1-22. Claims 55 and 56 describe blades pivotable between a smaller diameter configuration in which the blades are in a tangential orientation and a larger diameter configuration in which the blades are in a radial position by changing the direction of rotation of the cutter assembly. These features are described in the specification, for example, at page 36, lines 6-24.

It is urged that there is a clear basis in the specification as it was originally filed for all the above amendments, including the claim amendments and the new claims. Entry of the above amendments and new claims is respectfully requested.

### **Objections**

The drawings were objected to for failing to include reference numeral 96, and for showing certain reference numerals that were not described in the specification. Applicants have amended several of the figures to address these concerns. In view of the foregoing amendments, it is urged that the objection to the drawings may properly be withdrawn.

### **Rejections under §102(b)**

Claims 20, 25-29, 31, 32, 37 and 38 were rejected under 35 U.S. C. 102(b) as being anticipated by Wyzgala, et al., U.S. Patent No. 6,096,054. This rejection is respectfully traversed and applicant expressly does not acquiesce in this rejection. For purposes of clarifying applicants' claimed invention and expediting prosecution, however, many of the rejected claims have been amended. It is urged that the claims, as amended, are allowable in view of Wyzgala.

### **Independent Claims 20 and 28**

Claim 20, as amended, recites, among other things:

...an adjustable diameter cutter having a plurality of *radially pivotable* cutting blades, wherein *each of the cutting blades has a beveled edge for cutting*.  
(Amended claim 20, emphasis added).

Claim 28, as amended, recites, among other things:

...an expandable diameter cutter having a plurality of blades *pivotable between a tangential orientation and a radial orientation*.  
(Amended claim 28, emphasis added).

Applicants' adjustable cutter assembly employs a novel arrangement of *radially pivotable* blades that move between a tangential orientation in which the cutter assembly is in a smaller diameter condition and a radial orientation in which the cutter assembly is in a larger diameter condition. One way of adjusting the blades between the tangential and radial orientations is to change the direction of rotation of the drive shaft coupled to the cutter assembly. The ability to change the diameter of a cutter assembly is important because it permits the cutter assembly to be navigated to and from the internal material removal site in a smaller diameter condition in which it can traverse tortuous passageways, while it permits operation at the material removal site in a larger diameter condition to more effectively remove undesired material, such as atherosclerotic plaque or thrombus. Prior art devices have incorporated expandable cutter assembly capabilities, but none of the prior art devices or, to applicants' knowledge, none of the prior art publications, has disclosed or suggested the use of radially pivotable blades in such expandable cutter assemblies.

Wyzgala et al. teach several different types of expandable burrs. Figures 5, 6 and 7 illustrate adjustable ablation burrs having a plurality of flexible (leaf) blades secured at both ends, such that when the distance between the ends is changed (e.g. reduced), the blades flex (outwardly) to provide an expanded diameter burr. In general, changing the distance between the ends of the blades is accomplished using an indexing mechanism. The indexing mechanisms are slightly different in the embodiments of Figures 5, 6 and 7.

The Examiner, in connection with her comments regarding claim 25, states that the cutting blades (226) of Wyzgala et al. are pivotable on axes parallel to a central longitudinal axis of the cutter assembly to expand and contract. As noted previously, the cutting blades of Wyzgala et al. flex to expand and contract when the distance between the blade ends is changed. Applicants do not perceive, though, that the cutting blades of Wyzgala et al. *pivot* in the ordinary "turning" sense of the term pivot. Applicants' claim 20 has been amended to specify *radially pivotable* cutting blades, each of the cutting blades having a beveled edge for cutting. Claim 28 has been amended to specify blades that are *pivotable between a tangential orientation and a radial orientation*. It is not believed that Wyzgala et al. discloses or suggests cutting blades that are pivotable, or that are capable of pivoting between a tangential orientation and a radial orientation.

The Examiner makes numerous comments concerning various alleged teachings of Wyzgala et al. with reference to various of applicants' claims. Applicants do not believe it is necessary to address all of the comments specifically and expressly do not acquiesce in or agree with the Examiner's characterization of either the teachings of Wyzgala et al. or the applicants' previously pending claims.

It is urged that applicants' independent claims 20 and 28 are not disclosed, nor are they suggested by Wyzgala et al., and it is urged that applicants' claims 20 and 28, and all of the claims dependent therefrom are in condition for allowance.

### **Rejections under §103(a)**

Claims 21, 30 and 39 were rejected under 35 U.S.C. 103(a) as being unpatentable over Wyzgala et al., described above, in view of Clement et al., U.S. Patent No. 5,681,336. Claims 23 and 24 were rejected under 35 U.S.C. 103(a) as being unpatentable over Wyzgala et al., described above, in view of Clement et al. and further in view of Wulfman et al., U.S. Patent 5,584,843. These rejections are respectfully traversed.

The Examiner makes numerous comments concerning various alleged teachings of Clement et al. and Wulfman et al. with reference to various of applicants' claims. Applicants do not believe it is necessary to address all of the comments specifically and expressly do not acquiesce in or agree with the Examiner's characterization of either the teachings of the Clement et al. and Wulfman et al. patents, or the applicants' previously pending claims.

Neither Clement et al. nor Wulfman et al. disclose, or suggest, the use of pivotable blades in a cutter assembly for material removal from an internal body site. These references thus do not overcome the deficiencies of Wyzgala et al. with respect to important features of applicants' independent claims. It is therefore urged that applicants' dependent claims are allowable over the prior art of record.

### **Conclusion**

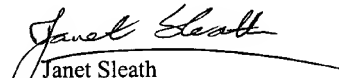
Accordingly, in view of the above amendments and remarks, it is submitted that pending claims 20, 21, 23, 24, 26-32 and 40-56 are now in condition for allowance. Early allowance is respectfully solicited. If the Examiner has questions or comments concerning the pending

claims, the claim amendments, the new claims or the prior art references, the Examiner is invited to contact **Ann W. Speckman** by telephone at **(206) 382-1191**.

*Charge Deposit Account*

Please charge any additional fees that may be required, or credit any overpayment, to our Deposit Account No. 19-3555.

Respectfully submitted,

  
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Date: March 2, 2004

**SPECKMAN LAW GROUP**

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